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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/616,301      | 07/10/2003  | Yoav Kimchy          | 25854               | 1622             |

7590 12/15/2006  
Martin D. Moynihan  
PRTSI, Inc.  
P.O. Box 16446  
Arlington, VA 22215

EXAMINER

CHAO, ELMER M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3737

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/616,301

Applicant(s)

KIMCHY ET AL.

Examiner

Elmer Chao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> .           |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 3, 4, and 6** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the phrase "narrow energy range" is indefinite and does not provide metes and bounds for the claims. The examiner will henceforth interpret "narrow energy range" as an energy range associated with a radioisotope.

**Claim 5 and 6** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 specifies "a shell which encapsulates said probe" (claim 1), whereas claim 5 specifies "said probe comprises a plurality of nuclear-radiation detectors, arranged around the external surface of said ingestible device" (claim 5). Claim 6 is dependent upon the claim 5, which makes claim 6 also indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-4 and 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Hassan et al. (Phys. Med. Biol., 1978, vol. 23, no. 2, 302-308). Hassan teaches “A Radiotelemetry Pill for the Measurement of Ionising Radiation using a Mercuric Iodide Detector” (title). Regarding claim 1, Hassan teaches that “the radiation pill consists of a mercuric iodide crystal, amplifier, transmitter, and a 1.35V battery” (last paragraph, pg. 303). Hassan teaches of “the pill’s plastic encapsulation” (last paragraph, pg. 306). Regarding claim 2, Hassan teaches that the “radiopill can also serve as a general purpose telemetric  $\gamma$ -ray detector” (last paragraph, pg. 302). Hassan teaches that “The radiopill was also tested as a beta detector” (first paragraph, pg. 307). Regarding claims 3 and 4, Hassan teaches that “the sensitivity of the pill has been found for  $^{99}\text{Tc}^m$ ,  $^{131}\text{I}$  and  $^{32}\text{P}$ ” (abstract). Regarding claim 7, Hassan does not teach the radiotelemetry pill with a collimator, nor does it even hint at the mercuric iodide crystal being collimated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 5 and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Barrett et al (U.S. 4,595,014), and in further view of Glukhovsky (U.S. 6,584,348). Hassan substantially discloses all the limitations as discussed above. Hassan does not disclose an ingestible device with a plurality of nuclear-radiation detectors arranged on the external surface of the ingestible device. However, Barrett ('014) teaches a nuclear radiation probe that includes multiple radiation detectors (C3, L51-53). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan to create an ingestible device with a plurality of nuclear-radiation detectors. Such a modification would help increase the area imaged are by not requiring the device to rotate fully in order to image the surrounding area (C3, L62-67). Glukhovsky ('348) teaches a capsule with electrode probes protruding out from openings of the capsule (Figure 2A). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan in view of Barrett ('014) to include a plurality of nuclear radiation detectors arranged around the external surface of the ingestible device. Such a modification would improve the sensitivity of

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the probes by not enclosing them by an encapsulation that could potentially attenuate the detectable radiation.

**Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan in view of Zhang et al. (Society of Nuclear Medicine, June 2000). Hassan substantially discloses all the limitations as discussed above. Hassan does not disclose an ingestible device arranged as a Compton camera. However, Zhang teaches a transrectal imaging probe based on Compton camera techniques (No. 68, second sentence). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Hassan to include a Compton camera probe as evidenced by Zhang. Such a modification would allow the ingestible device to have high sensitivity and high resolution (No. 68, second sentence).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC

11/13/2006

  
ELENI MANTIS MERCADER  
SUPERVISORY PATENT EXAMINER

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/25/2006 and 9/14/2005 and 12/1/2003.

Continuation of Attachment(s) 6). Other: Journal of Nuclear Medicine (1 page); "A Radiotelemetry Pill for the Measurement of Ionising Radiation using a Mercuric Iodide Detector" (7 pages).